SOUTHERN DISTRICT OF TEXAS
FILED
OCT 30 2006

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

DOUGLAS KAYE	§	
	§	
Plaintiff	§	
	§	
VS.	§	**CAUSE NO. 4:05-CV-02809**
	§	
SYNTHES (U.S.A.)	§	
	§	
Defendant	§	

MOTION FOR SUMMARY JUDGMENT
OF SYNTHES (U.S.A.)

TO THE HONORABLE UNITED STATES DISTRICT JUDGE:

Defendant, Synthes (U.S.A.) moves for summary judgment under Rule 56. This motion seeks a take-nothing judgment of dismissal against Plaintiff, Douglas Kaye for the reasons that follow.

I.
GROUNDS FOR SUMMARY JUDGMENT

Synthes (U.S.A.) is entitled to summary judgment on all of Plaintiff's claims because:

- there is no evidence of a manufacturing defect or any negligence in the manufacture of the subject product;
- Synthes (U.S.A.) met its duty with regard to warnings;
- there is no evidence of any negligence in design or of any design defect; and
- there is no causal evidence linking Plaintiff's damages to any product defect.

II.
STANDARD OF REVIEW

Synthes (U.S.A.) is entitled to summary judgment because there is no genuine issue of material fact about an essential element of each of Plaintiff's claims, be they sounding in negligence, strict product liability or breach of warranty. *Harris v. Rhodes*, 94 F.3d 196, 197-98 (5th Cir. 1996); *Meadowbriar Home, Inc. v. Gunn*, 81 F. 3d 521, 533 (5th Cir. 1996); Fed. R. Civ. P. 56. Moreover, summary judgment is particularly appropriate when certain questions to be decided (such as the proper application of a duty) are issues of law. *Flath v. Garrison Pub. Sch. Distr.*, 82 F.3d 244,246 (8th Cir. 1996).

III.
STATEMENT OF FACTS

In March 2003, Douglas Kaye collided with a tree while skiing in Vermont and was seriously injured, breaking no less than fifteen bones and collapsing a lung. Kaye Dep. 14-15.[1] Among Plaintiff's broken bones was a shattered left clavicle, surgical treatment for which is not normally required in adult patients. However, even after the passage of several weeks Mr. Kaye's clavicle failed to heal and was in danger of puncturing through the skin. Kaye Dep. 24-26. On March 24, 2003, he saw an orthopedic surgeon who declined to proceed with a surgical repair of the clavicle. Sitter Dep. 16-20; Kaye Dep. 24-26. However, by April, it was clear that Mr. Kaye's shattered clavicle was not likely to heal without surgery. Sitter Dep. 17-20. Indeed, what followed was a

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[1]References to Mr. Kaye's and to Dr. Sitter's (Plaintiff's treating physician and only designated medical expert) depositions are by name and page number – abbreviated thus: "Mr. Kaye Dep. #." A true and correct copy of these depositions are attached to and authenticated by the accompanying affidavit of Deanna Livingston, counsel for Synthes (U.S.A.).

References to the affidavits of Dr. Lemons and Dr. Labbé (which affidavits are filed herewith) are simply to the affidavit followed by a reference to the appropriate numbered paragraph. Thus, a reference to evidence contained in Dr. Labbé's affidavit is abbreviated "Labbé Aff. #."

course of four different surgeries, all of which were performed by Dr. Timothy Sitter in Sugar Land, Texas. Each of these surgeries involved implantation and/or explanation of one of three different internal bone fixation plates, all in an effort to effectuate healing of Plaintiff's broken clavicle. Kaye Dep. 70.

Synthes (U.S.A.) is a manufacturer and marketer of a wide variety of internal fixation devices, including bone plates similar to those selected and used by Dr. Sitter as part of his care and treatment of Plaintiff. Sitter Dep. 5-6. The purpose of these plates is to temporarily align and fixate the shattered bones along with any bone graft material. Sitter Dep. 16; Lemons Aff. 4. These plates are not intended to replace the broken bone, but rather to internally stabilize it so as to maximize the potential for bone healing. Sitter Dep. 16. If the bone does not heal, the plate is likely to break. Lemons Aff. 6. Indeed, it is "common knowledge" among the surgeons who choose and use internal fixation devices, such as the subject plate, that such plates can and will break in the absence of a product defect. Sitter Dep. 14-16; Labbe´ Aff. 7; Lemons Aff. 4 and 6.

In Plaintiff's case, non-surgical treatment (the norm for adult clavicular fractures) failed, and Dr. Sitter first attempted internal fixation on April 14, 2003. Sitter Dep. 20-22. As part of this surgery, Dr. Sitter chose a 6-hole bone fixation plate manufactured by Smith and Nephew. Sitter Dep. 23. The size (particularly the width and thickness) of this plate caused Plaintiff discomfort. Sitter Dep. 27-28. In an attempt to address this concern, Dr. Sitter removed the Smith and Nephew plate and performed an osteotomy on June 23, 2003. Sitter Dep. 29. An osteotomy involves a surgical cutting and realignment in a "fracture" or break. Sitter Dep. 28-29. In performing this procedure, Dr. Sitter hoped "to get rid of his [Plaintiff's] irritating symptoms by removing the plate and reducing the bone volume if possible in an effort to even it out and make it more flat and smooth

so it wasn't rubbing." Sitter Dep. 28. Because of the large amount of bone removed from an already comprised clavicle, Dr. Sitter applied another internal bone fixation plate, albeit a much smaller, thinner, lower profile one. Sitter Dep. 29-30, 34. The smaller plate is the product that is the subject of this lawsuit. This plate is described as a Synthes one-third tubular plate with collar, and it was chosen by Dr. Sitter without consultation with Synthes. Sitter Dep. 34.

Dr. Sitter cannot remember what warnings or activity limitations he provided to Plaintiff following implantation of the subject plate. Sitter Dep. 95-97. Likewise, Plaintiff does not remember any restrictions or instructions to prevent breakage of the smaller plate that had just been implanted on his newly "rebroken" clavicle. Kaye Dep. 76-78. However, Plaintiff returned to work as a manual scissor sharpener within a few days following the implantation of the subject plate. Sitter Dep. 43; Labbe´ Aff. 7; Lemons Aff. 5. Manuel scissor sharpening involves repetitive application of pressure by his hands, arms and shoulders. Kaye Dep. 55-57; Lemons Aff. 5. Such repetitive application of pressure creates high number of loading cycles to the bone and plate region. Lemons Aff. 5. The plate was further stressed when, on July 28, 2004, Plaintiff moved a full refrigerator. Kaye Dep. 87-88; Lemons Aff. 5. Later that evening, his shoulder began hurting. Kaye Dep. 89. The next day, x-rays showed that the smaller plate implanted five weeks earlier, had broken. Sitter Dep. 41. On July 30, 2003, Dr. Sitter surgically removed the broken plate which has since been lost to both parties.[2] Kaye Dep. 96; Sitter Dep. 71.

During the removal surgery (Plaintiff's third clavicle surgery), Dr. Sitter noted that Plaintiff's clavicle showed no evidence of healing, indicating a potential for a delayed union. Sitter Dep. 45. At that time, Dr. Sitter chose another Synthes plate. However, this time he opted for a Synthes plate

[2]Similarly, all x-rays or other radiographic films of Plaintiff's clavicle have been lost. Sitter Dep. 59-61; Kaye Dep. 26-28.

that was both thicker and stronger than the subject plate. Sitter Dep. 50, 53. Because of the thickness of this third plate, Dr. Sitter expected that it would cause discomfort to Plaintiff and would need to be removed once Plaintiff had healed. Sitter Dep. 56. By May 12, 2004, Plaintiff had adequately healed, and Dr Sitter removed the third plate. Sitter Dep. 75-76. Plaintiff has since experienced no problems with his clavicle or shoulder. Kaye Dep. 103.

IV.
SUMMARY OF THE ARGUMENT

This Court should grant judgment in favor of Synthes (U.S.A.) because Plaintiff has wholly failed to bring forth evidence of the prerequisites for a product liability case (be it based on strict product liability, negligence, or breach of warranty law). Plaintiff's manufacturing defect claims fail because there is and there can be no evidence that the product (in this case the subject plate) deviated, in terms of construction or quality, from specifications or planned output in a manner that renders it unreasonably dangerous. Importantly, every expert has testified that the simple fact that the plate broke is not evidence of any defect in the plate. The fact of the matter is that bone fixation plates can and do break in the absence of any product defect. This fact is recognized in the medical literature and is taught to orthopedic surgeons early in their residencies.

Plaintiff's marketing defect claims likewise fail because Plaintiff has yet to bring forth evidence that the package insert which accompanied the subject product – a prescriptive medical device – was inadequate to the point of being unreasonably dangerous. Nor has Plaintiff proposed alternative warnings or instructions for safe use. The undisputed evidence is that orthopedic surgeons generally, and Dr. Sitter in particular, already knew that internal bone fixation plates can and will break in certain conditions. In fact, Dr. Sitter has known all of the information in the package insert applicable to the subject plate since his first year as a resident in orthopedics. Further,

Dr. Sitter felt in 2003 that he had all of the information available to him that he felt was necessary in choosing the subject plate. Because there is no duty to warn a user of something he already knows or should know, Synthes (U.S.A.) cannot be liable.

Turning to the claim of a design defect, Plaintiff has ignored the well-established Texas law requiring him to prove the subject plate was unreasonably dangerous, after balancing its risk against its utility. All of the medical evidence is that the design was appropriate and that the plate posed no unreasonable risk of harm. Further, Plaintiff has not even proposed an alternative design, much less provided evidence that any alternative design would be both safer and feasible. Moreover, because there is no evidence that Dr. Sitter would have used any theoretical alternative design or that any theoretical alternative design would not have broken – Plaintiff fails to provide the requisite causal nexus on his design defect claims.

V.
ARGUMENT

A. No Evidence Exists of a Defect or of any Negligence in Manufacturing.

In order to succeed in his claim of a manufacturing defect (or "impure product"), Plaintiff must first establish that the product (in this case the subject plate) deviated, in terms of construction or quality, from specifications or planned output in a manner that renders it unreasonably dangerous to a patient such as Douglas Kaye. Once such a deviation from the specifications or planned output has been identified in the product(s), a plaintiff must then establish the requisite causal connection between the defective condition and the alleged injuries or damages. *American Tobacco Co., Inc. v. Grinnell*, 951 S.W.2d 420 (Tex. 1996).

There is, and there can be, no evidence brought by Plaintiff to show any deviation in the product as manufactured from its specifications or planned output for the simple reason that the

subject plate has been lost. As a result of the loss of the very product which is the basis of Plaintiff's claims, no inspections, testing or comparison with any pertinent specifications can be made. Simply put, without such tests, inspections and comparisons, no evidence can exist to support a claim of a manufacturing defect.

The fact that the subject plate broke is not evidence of any defect – manufacturing or otherwise. Labbe´ Aff. 7-8; Lemons Aff. 7. Instead, the fact that such plates can, and occasionally do, break is well recognized by the community of surgeons using these products and performing these procedures. Sitter Dep. 14-15, Labbe´ Aff. 7; Lemons Aff. 4. Such plate breakages can occur in the absence of manufacturing defects and in the absence of any negligence on the part of either the product supplier or the implanting surgeon. Sitter Dep. 15-16, Labbe´ Aff. 7, 8; Lemons Aff. 5, 7. Thus, plate breakage is not evidence of a manufacturing defect; and, without the plate, there can be no evidence of a manufacturing defect.

B. Synthes (U.S.A.) Met Its Duty with Regard to Warnings

In Texas, a marketing defect exists only if the failure to provide instructions and warnings rendered the product(s) "unreasonably dangerous." To be unreasonably dangerous, the plate must be "dangerous to an extent beyond that which would be contemplated by the ordinary prescribing surgeon of the product with the ordinary knowledge common to the medical community as to the product's characteristics. *See American Tobacco Co., Inc. v. Grinnell*, 951 S.W.2d 420, 426 (Tex. 1997) (no liability "unless a product is dangerous to an extent beyond that which would be contemplated by the ordinary consumer with knowledge common to the community").

Further, "the existence of a duty to warn of the dangers of an alleged defective product is a question of law." *Firestone Steel Products Co. v. Barajas*, 927 S.W.2d 608, 613 (Tex. 1996). As

a matter of law, a manufacturer or distributor has no duty to warn of "obvious" risks that are "generally known and recognized" and "within the ordinary knowledge of the community." *Joseph E. Seagram & Sons, Inc. v. McGuire,* 814 S.W.2d 385, 387 (Tex. 1991); accord *American Tobacco Co. v. Grinnell*, 951 S.W.2d 420, 426 (Tex. 1997); *Saunder Custom Fabrication, Inc. v. Boyd*, 967 S.W.2d 349, 349 (Tex. 1998); *Catepillar, Inc. v. Shears,* 911 S.W.2d 379, 382 (Tex. 1995). The "obviousness of a risk" is to be determined from the standpoint of "an average user of the product." *Saunder Custom Fabrication*, 967 S.W.2d at 349.

In this case, the bone plate in question is a prescriptive medical device for which, the learned intermediary doctrine is applicable and has been duly pled by Synthes (U.S.A.). For purposes of warning, the doctrine identifies that person who should have received the warning and whether the warning was sufficient in that context. *Reyes v. Wyeth Labs, Inc.*, 498 F.2d 1264 (5th Cir. 1974) cert. denied, 419 U.S. 1096 (1974). In this case, the average user of the product — the person who was to receive any necessary warnings and/or instruction for safe use — comes from the community of operating surgeons who are trained and experienced in internal bone fixation. Thus, Synthes (U.S.A.)'s duty to warn is a duty to warn average/reasonable prescribing surgeons.

Synthes (U.S.A.) provided such warnings to prescribing surgeon in the form of its package insert (a copy of which is attached to and authenticated by the Affidavit of Dr. Marc R. Labbé and the deposition of Dr. Timothy Sitter). Synthes (U.S.A.)'s package insert was provided with the subject plate. Sitter Dep. 111. Moreover, the information contained in this document was fully known to Dr. Sitter at the time that he selected and implanted the subject plate as part of his surgical care and treatment of Mr. Kaye. Sitter Dep. 93.

Synthes (U.S.A.)'s package insert includes four specifically numbered warning paragraphs

and an equal number of specific precautions. The first warning paragraph includes a warning that "metallic internal fixation devices cannot withstand activity levels or loads equal to those placed on normal healthy bone." This warning goes on to state in bold, underlined type that "these devices are not designed to withstand the unsupported stress of full weight bearing or load bearing." The package insert further warns that "these devices can break when subjected to the increased loading associated with delayed union or non-union."

Synthes (U.S.A.)'s package insert undisputably gives implanting surgeons specific warnings about the use of the subject plate – warnings which Dr. Sitter admits to knowing prior to his implantation of the subject plate. Sitter Dep. 81-81, 93, 111. Because, by law, these warnings were appropriately given to a prescribing surgeon, they anticipate that the learned intermediary will consider and apply them to the particular circumstances for which the internal fixation device is prescribed. To that end, the package insert advises, in precaution number four, that the surgeon "adequately instruct the patient" about the characteristics and use of the particular internal fixation device, and continues with a list of possible adverse effects, the first of which is a statement that certain conditions can lead to breakage of the implant. Although Dr. Sitter cannot remember what warning and instructions he provided to Plaintiff (Sitter Dep. 95-97) nor can Plaintiff remember receiving any specific warnings or instructions from Dr. Sitter (Kaye Dep. 76-78), Synthes (U.S.A.)'s warnings were legally sufficient and medically appropriate.

Additionally, a manufacturer or distributor has no duty to warn of dangers that are actually known by the user: "the duty to warn is limited in scope and applies only to hazards of which the consumer is unaware." *Catepillar*, 911 S.W.2d at 382. As Texas Courts have long recognized, "no recovery right exists when the party to be warned is already aware of the danger." *USX Corp. v.*

Salinas, 818 S.W.2d 473, 483 (Tex. App.–San Antonio 1991, writ denied). A "warning is required in order to impart special knowledge. If that special knowledge already exists, further information is not necessary." *Munoz v. Gulf Oil Co.*, 732 S.W.2d 62, 66 (Tex. App.–Houston [14th Dist.] 1987, writ ref'd n.r.e. In this case, Dr. Sitter unequivocally acknowledges that he had "all of the information available" to him that he felt was necessary in choosing the subject plate "over any other method of fixation." Sitter Dep. 82. Thus, Synthes (U.S.A.) can legally owe no duty to warn Dr. Sitter of that which was already known to him. Lacking a legal determination of duty, summary judgment is mandated.

C. The Subject Plate's Design is Appropriate and Plaintiff has Proposed No Safer Alternatives.

Without being specific or in any way proposing alternatives, Plaintiff implies that the subject plate was defective in its design, and, presumably, and such unspecified defect is the cause of Plaintiff's injuries. There is, however, no evidence to support such a claim – whether sounding in negligence or strict product liability – and these claims of plaintiff likewise fail as a matter of law for the following reasons.

1. There is No Evidence of any Negligence in Design.

First, the plate in question in this suit was not designed by Synthes (U.S.A.). Thus, there is and there can be, no evidence of negligence in the design so as to confer liability on Synthes (U.S.A.)

2. There is No Evidence of any Design Defect.

Moreover, "[t]he law of products liability does not guarantee that a product will be risk free, since most products have some risk associated with their use." *Catepillar, Inc. v. Shears*, 911 S.W.2d 379, 381 (Tex. 1995). A manufacturer or distributor of products is not an "insurer" and is not required to design "the safest possible product." *Accord v. General Motors Corp.*, 669 S.W.2d

111, 114 (Tex. 1984) (citing cases), quoted in *Ford Motor Co. v. Miles*, 967 S.W.2d 377, 386 (Tex. 1998). Nor must a product design "be the best that science can produce." *Henderson v. Ford Motor Co.*, 519 S.W.2d 87, 93 (Tex. 1974).[3]

The RESTATEMENT (THIRD) OF TORTS provides that a prescriptive medical device is unreasonably dangerous due to a defective design *only* if the foreseeable risks of harm posed by the ... medical device are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the ... medical device for *any* class of patients." RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(c) (1998) (emphasis added). As the comments to this section recognize, "given this very demanding objective standard, liability is likely to be imposed only under unusual circumstances." *Id.* at § 6 cmt f. Further, the Court, not the jury, "has the responsibility to determine when the plaintiff has introduced sufficient evidence so that reasonable persons could conclude that plaintiff has met this demanding standard. *Id.*

In this case, Plaintiff has not and cannot meet this standard. In fact, the evidence before this Court is that this plate is "well-designed" (Sitter Dep. 80-81) and "remains an appropriate choice for certain patients" (Sitter Dep. 37). Another orthopedic surgeon avers that he extensively uses the subject type of plate and would not do so if he had any doubts about the plate's design. Labbé Aff. 4. Plaintiff has not even attempted to provide evidence that reasonable health-care providers would not prescribe a Synthes one-third tubular plate with collar for any class of patients or that the design

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[3] *Henderson* has been overruled on other grounds by *Accord v. General Motors Corp.*, 669 S.W.2d 111 (Tex. 1984), *Duncan v. Cessna Aircraft Corp.*, 664 S.W.2d 414 (Tex. 1984), and *Turner v. General Motors Corp.*, 584 S.W.2d 844 (Tex. 1979). *Henderson*, however, remains in force for the points for which it is cited in this motion, as shown by its citations with approval in *Ford Motor Co. v. Miles*, 967 S.W.2d 377, 386 (Tex. 1998).

of this plate is in any way defective. Nor can he do so. Dr. Sitter believes that the subject plate was an "appropriate choice for his care and treatment" of Mr. Kaye and was "reasonably fit for its intended purpose." Sitter Dep. 37. Further, Dr. Sitter continues to use Synthes one-third tubular plates today and believes that this type of plate "remains an appropriate choice for certain patients, depending upon their fracture patterns and individual medical characteristics or circumstances." Sitter Dep. 37. In short, Dr. Sitter does not believe that the subject type of plate poses an unreasonable risk of harm to the patients for whom it is prescribed (Sitter Dep. 38-40) and that "it's a well-designed plate for what I use it for." Sitter Dep. 80-81. Likewise, Drs. Labbe´ and Lemons both support the appropriateness of the subject plate's design. Labbe´ Aff. 4; Lemons Aff. 7.

Further, Plaintiff has provided no evidence of any alternative, feasible design for the subject plate. Synthes (U.S.A.) contends, and Drs. Labbe´, Sitter and Lemons provide evidentiary support, that the current design is an appropriate design – mechanically, medically and economically – for the use intended for the product. Texas law requires that any determination that a design is unreasonably dangerous requires balancing the utility of the product against the risk involved in its use. *Catepillar, Inc. v. Shearn*, 911 S.W.2d 379, 384 (Tex. 1995). In order to meet this balancing test, the party complaining of the design must show by material evidence that the current design is defective, that there is a safer design which is scientifically or mechanically feasible and that the alternative design is economically feasible. *See, Catepillar* at 384. Absent genuine material evidence of an alternative design, more effective and economical design, summary judgment on the issue of design defect should be granted.

3. There is No Evidence that Any Design Defect Was a Producing Cause of Mr. Kaye's Alleged Injuries.

Under either a producing cause or proximate cause standard, a plaintiff must prove "actual

causation in fact." *Prudential Ins. Co. v. Jefferson Assoc. Ltd.*, 896 S.W.2d 156, 161 (Tex. 1995). Proof of causation in fact "requires proof that an act or omission was a substantial factor in bringing about an injury which would not otherwise have occurred." *Id.* (emphasis added). If the injury would have occurred anyway, the defendant did not cause the injury and cannot be held liable for any damages. *Id.*

Plaintiff offers no evidence that Dr. Sitter would have used any alternative design. Failure of this proof is dispositive because the choice of treatment — specifically the choice of which, if any, bone fixation plate to use — is a choice to be made by the treating orthopedic surgeon. Thus, Plaintiff has brought forth no evidence that any alleged design defect in the Synthes plate caused Mr. Kaye' injuries.

Further, Plaintiff offers no evidence that any design alternative would have prevented Mr. Kaye' injuries. There is no evidence and there can be no evidence that given Mr. Kaye' physical condition, such an alternately designed plate would not have broken. In the absence such of evidence, Plaintiff fails in his claims that an alleged design defect was a cause in fact of Mr. Kaye' injuries.

D. The Subject Plate was Merchantable.

For reasons similar to those set out in sections I through III, Plaintiff's claims of breach of the implied warranties of merchantability and fitness for a particular purpose necessarily fail and Synthes (U.S.A.) is entitled to summary judgment on this issue as well. Without conceding that warranties were made or that Synthes (U.S.A.) was a "merchant" as that term is defined in Tex. UCC § 2.104(a), Plaintiff can offer no evidence that the subject plate was anything other than fit for the ordinary purposes for which such prescriptive medical devices are used. Indeed, all of the available evidence supports the general fitness of this plate which was specifically chosen by Plaintiff's own

surgeon who has testified that the plate was both merchantable and fit for the purpose he intended.

E. There is No Causal Link Between the Subject Plate and Any of Plaintiff's Damages.

All evidence negates any causal link between any alleged defect in the subject plate and any damages suffered by Plaintiff. More succinctly, Plaintiff has attempted to only link his claimed damages[4] to the breakage of the subject plate. Plaintiff has not produced the required expert testimony that any product **defect or act** by Synthes (U.S.A.) (as opposed to a plate breakage in the absence of a defect or negligence) was a producing cause of Mr. Kaye's injuries. In the absence of such evidence, and in the presence of competent expert testimony specifically negating causation, Plaintiff fails in all of his claims against Synthes (U.S.A.).

This is true because under either a producing cause or proximate cause standard, Plaintiff must prove "actual causation in fact." *Prudential Ins. Co. v. Jefferson Assoc. Ltd.*, 896 S.W.2d 156, 161 (Tex. 1995). Proof of causation in fact "requires proof that an act or omission was a substantial factor in bringing about an injury which would not otherwise have occurred." *Id.* If the injury would have occurred anyway, the defendant did not cause the injury and cannot be held liable for any damages. Id. In this case, Drs. Sitter and Labbé both specifically negate causation by testifying that "any medical expenses or other related damages experienced by Mr. Kaye . . . flow from and were caused by his skiing accident" not the breakage of the plate which Dr. Labbé averred was defect-

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[4]Plaintiff has disavowed any claims of damages arising from future medical expenses, as well as any lost wages or lost earning potential. In Mr. Kaye's own words, he brought this lawsuit because he felt that he had "risked" his life by undergoing the surgery to remove the broken plate. (Kaye Dep.13, 103-104.) Such a fear is insufficient under Texas law to support a claim for damages. Moreover, Plaintiff experience none of the complications associated with anesthesia or surgery in connection with either of the clavicle surgeries following breakage of the subject plate. Indeed, Plaintiff has successfully healed, thus demonstrating why such fears of unrealized harm are not the proper subject of damages.

free. Labbé Aff. 8. Given the specific evidence negating a causal link between any product defect or act by Synthes (U.S.A.) and any of Plaintiff's damages, all of Plaintiffs' claims fail. Synthes (U.S.A.) is entitled to judgment as a matter of law.

PRAYER

For the foregoing reasons, Synthes (U.S.A.) prays that the Court grant its motion for summary judgment. Synthes (U.S.A.) prays for all relief to which it may be entitled.

Respectfully submitted,

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CERTIFICATE OF SERVICE

A true and correct copy of the above and foregoing pleading was duly served upon all parties or their counsel of record by messenger, facsimile, or by placing same in the United States Mail, postage prepaid, properly addressed to the counsel of record, on this the 30th day of October 2006.

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Via Hand Delivery

DEANNA H. LIVINGSTON